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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,035	BIGNON ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/16/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-42* is/are pending in the application.

4a) Of the above claim(s) *1,2,8,16 and 27-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,9,10,12-15,17-26 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/16/2010 (referring back to the non-responsive submissions filed on 11/9/2009 and 3/1/2010) has been entered.

Formal Matters

2. Applicant's Response filed 11/09/2009 are acknowledged and entered. Claim 11 has been cancelled by Applicant. New claims 41 and 42 have been added. Claims 1-10 and 13-42 are pending. Claims 1, 2, 8, 16, and 27-34 are withdrawn as being drawn to non-elected inventions. Claims 3-7, 9, 10, 12-15, 17-26, and 35-42 are under examination as they are drawn to the species of Formula I.

Response to Arguments

Objections/Rejections Withdrawn

3. Rejections drawn to cancelled claim 11 are moot in light of the cancellation of the claim.

4. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicant's amendments.

Objections/Rejections Maintained

Claim Rejections - 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 24 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that claim 24 has been amended to overcome the rejection (Remarks, p. 22).

Applicant's arguments have been fully considered, but they are not persuasive. Claim 24 contains a broad recitation of "proteins" followed by alternative narrow recitations of specific "peptides."

Similarly, the claim recites both "oligonucleotides" and "polynucleotides." The broad recitation of proteins and polynucleotides and the narrower recitations of oligonucleotides and peptides render the metes and bounds of the claim unclear and indefinite. Applicant is once again referred to *Ex parte Miyazaki* (BPAI 11/19/2008), especially at Slip Op. 11-12.

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 3-7, 9, 10, 12-15, 17-26, and 35-40 remain rejected and new claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an IL-2 formulation comprising a polyglutamate polymer grafted with α-tocopherol which spontaneously associates with bovine serum albumin to form a gel *in vitro* and *in vivo* in a concentration-dependent manner, does not reasonably provide enablement for the claimed super genus of structural variants comprising at least one active principle (AP) and a biodegradable polymer (PO) carrying hydrophobic groups (HG) or the super-genus of biodegradable polymers of Formula I, for the reasons of record and the reasons set forth herein.

Applicant argues that the claim amendments to limit the hydrophobic groups is sufficient to overcome the instant rejection (Remarks, p. 22). Applicant argues that the structure of the hydrophobic group is not relevant to the claimed invention and that the only technical features that need to be considered to achieve the claimed invention are the chemical properties of the hydrophobic groups, namely their hydrophobicity (Remarks, p. 24). Applicant's arguments have been fully considered, but they are not persuasive. As stated of record, the rejection stated that the specification does not reasonably provide enablement for the claimed super genus of structural variants comprising at least one active principle (AP) and a biodegradable polymer (PO) carrying hydrophobic groups (HG) or the super-genus of biodegradable polymers of Formula I. Applicant has limited one of the supergeneras, but has not further limited the other recited generas such that the skilled artisan would be reasonably apprised of how to make and use Applicant's invention without undue experimentation. Recitation of three hydrophobic groups are insufficient to provide enabling support for the numerous genera of structural variants comprising at least one AP and a PO or the generas of biodegradable polymers.

Applicant also argues that the active principle is not the core element of the invention and that there is not requirement regarding the nature or the concentration of the active principle, but rather the gelling formulation is the critical component (Remarks, pp. 22-23). Additionally, Applicant states that the composition is not limited to interleukins and many different active principles could be incorporated in the same gelling formulation (Remarks, p. 23). The examiner understands this point and it is precisely for this reason that Applicant has not sufficiently taught how to make or use the invention commensurate in scope with the claims. The determination of whether Applicant has met his burden of disclosing how to make and use the invention to the public in order to satisfy the *quid pro quo* requirement of disclosure in exchange for a patent has not been adequately met by the instant claims or specification. From the early days of the republic, our patent law has required that in exchange for a government-sanctioned monopoly on the rights to an invention or discovery, the inventor must teach the world the secret behind the method or device. Compare 35 USC § 112 (1984) with Act of April 10, 1790, ch. 7, § 2, 1 Stat. 109 ("specification shall be so particular . . . as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art of manufacture . . . to make, construct or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term"); see also, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146-51, 103 L. Ed. 2d 118, 109 S. Ct. 971 (1989); *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (specification must teach how to make and use the invention as broadly as it is claimed). The rationale for the enablement requirement is that an inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge. He may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186-87, 77 L. Ed. 1114, 53 S. Ct. 554 (1933) (citations omitted); see also *O'Reilly v. Morse*, 56 U.S. 62, 119-20, 14 L. Ed. 601, (15 How. 62, 127-28) (1853) (Taney, C.J.) (one skilled in the art must be able to produce precisely the described result by using the means specified by the inventor); *Grant v. Raymond*, 31 U.S. 217, 247 (31 Peters 141, 160) (1832) (Marshall, C.J.) (correct specification is a prerequisite to obtaining a patent in order to give the public "the advantage for which the privilege is allowed, and is the foundation of the power to issue the patent."). When a putative inventor fails or refuses to fulfill the obligation to teach precisely what is claimed, the inventor is not entitled to the protections of the patent law. See, e.g., *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469-70 (Fed. Cir. 1993) (affirming determination of lack of enablement where fifty examples in specification "obviously teach something," but not what was defined in the claims).

Applicant argues that hydrophobically modified polyamino acids have been well known and described in the art (Remarks, p. 24). Applicant argues that there is no undue burden for the person skilled in the art to synthesize such polymers in order to associate them to active principles in the conditions of the claimed invention (Remarks, p. 24). Applicant's arguments provide no additional clarification or guidance as to the claimed supergeneras. Applicant provides no evidentiary showing that the breadth or the scope of the claims, as written, have enabling support in the prior art for the full scope of the claims. Applicant's arguments tend to support the examiner's position that neither the claims nor the specification provide sufficient starting material and are nothing more than an invitation to further experimentation to arrive at the claimed composition.

Applicant argues that no discrete species is required in the description to illustrate the invention as long as the invention can be understood and reproduced (Remarks, p. 24). Applicant is mistaken in this regard. As explained of record, the only active principle (AP) recited in the claims is "an interleukin." Applicant has admitted in the Response filed 11/9/2009 that the genus of interleukins is only one embodiment and that any other generic active principle may be encompassed by the claims (see Remarks, p. 23). The examples in the specification for active principles on page 23 are non-specific, generic generas, including "proteins." Applicant has not shown a sufficient number of representative species of proteins to fully enable the claimed genus commensurate in scope with the claims. Applicant is reminded that Broad claims may be rejected merely because they read on a significant number of inoperative species when examiner sets forth reasonable grounds in support of his or her conclusions that the claims may read upon inoperative subject matter and it becomes incumbent upon applicant either to reasonably limit claims to approximate area where operativeness has not been challenged or to rebut examiner's challenge by submission of representative evidence or by persuasive arguments based on known laws of physics and chemistry (see *In re Cook and Merigold*, 169 USPQ 298 (CCPA 1971)).

Applicant argues that claim 23 limits the at least one active principal to IL-2 (Remarks, p. 25). Applicant's argument is not persuasive. Claim 23 only limits the interleukin to IL-2, but claim 3 recites "at least one active principle" is an interleukin. Accordingly, claim 23 does not limit the number or kind of active principles in the composition, so long as IL-2 is included. Additionally, Claim 23 does not otherwise limit any of the other generic components of the composition including the water-soluble biodegradable polymers, surfactants, or physiological electrolytes.

Applicant argues that claim 24 has been amended and new claims 41 and 42 have been added (Remarks, p. 25). These changes are noted, but they are insufficient to overcome the instant rejection. New claims 41 and 42 are also rejected herein because although they recite genera from claim 24, they do

not recite species nor do they otherwise limit any of the other generic components of the composition including the water-soluble biodegradable polymers, surfactants, or physiological electrolytes.

As stated of record, the suggestion of Applicant's representative that a skilled artisan make and test any generic number of the generic formulations is tantamount to an invitation to experiment. See *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). Such an invitation does not constitute an enabling disclosure.

Due to the large quantity of experimentation necessary to determine how to make or use the claimed supergenera of compositions without resorting to undue experimentation to determine the structure of the composition or how to make or use it *in vitro* or *in vivo*, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite a specific structure or composition, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3-7, 9, 10, 12-15, 17-26, and 35-40 remain rejected and new claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record and the reasons set forth herein.

Applicant disagrees with the examiner's rejection and argues that the amendments to specify the hydrophobic groups are sufficient to overcome the rejection (Remarks, p. 25). Applicant argues that the other limitations of the claims are sufficient to meet the written description requirements because the claimed invention has the same physical properties - being the ability to form gelled deposits in an aqueous solution comprising bovine serum albumin in a concentration of 30 mg/ml (Remarks, p. 26). Applicant's argument has been fully considered, but it is not persuasive. Notwithstanding Applicant's amendments, Applicant admits that the structure of the hydrophobic group is not relevant to the claimed invention and that the only technical features that need to be considered to achieve the claimed invention are the chemical properties of the hydrophobic groups, namely their hydrophobicity (Remarks, p. 24).

Applicant's arguments that the other generic limitations are sufficient to meet the possession requirement is not accepted. Applicant is claiming a composition comprising multiple components. Applicant's arguments that a description of the precise components of the composition are irrelevant as long as the composition comprises 30 mg/ml of BSA is not well taken. Applicant is, in essence, arguing that all compositions of matter are encompasses within the claims as long as 30 mg/ml of BSA are present and the polymers are of sufficient hydrophobicity to form gels. Applicant has not provided an adequate description to show that Applicant was in possession of a sufficient number of representative species to show that Applicant was in possession of the scope of subject matter as claimed. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord *Ex Parte Kubin*, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

As stated of record, conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, at 1206, 18 USPQ2d 1016, at 1021 (Fed. Cir. 1991). In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor's idea of the invention. *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994). Reduction to practice in effect provides the only evidence to corroborate conception (and therefore possession) of the invention. *Id.*

Applicant is also referred to *Ariad Pharmaceuticals Inc. et al., v. Eli Lilly and Co.*, Slip Op. 2008-1248 (Fed. Cir. 3 April 2009), especially at p.7, stating that "the written description requirement is not satisfied by the appearance of mere indistinct words in a specification or a claim, even an original claim…A description of what a material does, rather than of what it is, usually does not suffice" quoting *Enzo Biochem Inc., v. Gen-Probe Inc.*, 323 F. 3d 956, 968 (citing *Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1159, 1568 (Fed. Cir. 1997) and *Univ. of Rochester v. G.D. Searle & Co*, 358 F3d. 916, 926 (Fed. Cir. 2005). In *Ariad*, the Court held that to satisfy the written description requirement for the asserted claims, the specification must demonstrate that Applicant possessed the claimed methods by

sufficiently disclosing the structure of the molecules capable of performing the disclosed function, citing *Capon v. Eshhar*, 418 F.3d 1349,1357 (Fed. Cir. 2005) (*Ariad*, Slip Op. at 10).

The concerns raised by the examiner specifically relate to aspects of Applicant's generic invention which are not adequately described. Applicant is encouraged to review the recent decision in *Carnegie Mellon University et al., v. Hoffman-La Roche, Inc.,* et al., Slip Op. 2007-1266 (Fed. Cir., 8 September 2008), where the CAFC specifically addressed the issue of generic claims to biological and chemical subject matter. The Court stated that "[t]he basic function of a patent specification is to disclose an invention. It has long been the case that a patentee can lawfully claim only what he has invented and described, and if he claims more his patent is void'" (citing *O'Reilly v. Morse*, 56 US (15 How.) 62, 121 (1853)) (Slip Op., at 10). "The written description serves a *quid pro quo* function 'in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time'" (citing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004), quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F3d 956, 970 (Fed. Cir. 2002) (Slip Op., at 10). The *Carnegie Mellon* Court held that "[o]ne must show that one has possession, as described in the application, of sufficient species to show that he or she invented and disclosed the totality of the genus" (Slip Op., at 18).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 3-7, 9, 10, 12-15, 17-26, and 35-40 remain rejected and new claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huille et al., WO 00/30618 (published 2 June 2000) (cited on Applicant's IDS of 9/21/2006) (the English language translation of which is US Patent 6,630,171) (see Patent family history for WO 00/30618, last accessed 11/28/2008), Lambert et al., US Patent 7,030,155 (benefit to 5 June 1998), and Singh et al., US Patent 5,102,872 (7 April 1992), as evidenced by the Handbook of Chemistry and Physics, 88th Ed., 2008 (Viscosities of Liquids, Section 6, pages 175-179) and Akiyoshi, et al., (J Controlled Release. 1998;54:313-320), for the reasons of record and the reasons set forth herein.

Applicant argues that none of the cited references alone or in combination teach or suggest 30 mg/ml of BSA sufficient to render the claims obvious (Remarks, p. 26). Applicant argues that Huille does not teach BSA at 30 mg/ml (Remarks, p. 27). This fact was pointed out by the examiner in the prior Office Actions.

Applicant argues that Singh does not cure this deficiency (Remarks, p. 27). Applicant argues that Singh does not teach BSA (Remarks, p. 27). Applicant is referred to column 5, line 64, wherein Singh indicates BSA as an equivalent of BSA for use in extended release gelling compositions.

Applicant argues that the serum albumin of Singh would not be more than 20% be weight and that the claims require the dried composition be more than 30% serum albumin by weight before a liquid is added in order for the claimed invention to have 30 mg/ml serum albumin (Remarks, p. 27). Applicant is referred to column 6, lines 2-5, which specifically states, "[t]he precise quantity of HSA will vary depending on the exact form of HSA (or equivalent), IL-2, and polymer, but will generally be within the ratio range of about 1:5 to about 1:30 IL-2-HSA by weight." The direct teaching of Singh is prima facie evidence to support the inclusion of 30mg/ml of BSA or alternatively to clearly permit reasonable and obvious variations of the amount of BSA used. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Applicant argues that one would not increase BSA concentration to optimize the teachings of Singh because Singh teaches that having a higher protein loading level tends to cause enhanced initial burst release (Remarks, pp. 27-28). Applicant's argument is misplaced. The teachings at column 7 to column 8 of Singh ("B. General Method"), do not refer to the HSA when it refers to "protein." Instead, it refers to the PEGyl-IL-2. This is confirmed by the teachings at column 8, lines 57-59, which states that "the microcapsules contain 0.5-20% PEGyl-hIL-2 encapsulated in PLG with a release-modifying amount of HSA." This amount of PEGyl-IL-2 at column 8, lines 57-59 correlates directly with the PEGyl-IL-2 at column 8, lines 2-3. Moreover, column 8, lines 58-59 reinforce the teaching that the HSA (or equivalent) will be in a release-modifying amount.

Applicant argues that Singh does not teach a gelled deposit in the presence of serum albumin and that Huille does not cure this deficiency (Remarks, p. 28). Applicant is reminded that the rejection is made under 35 USC 103(a) and the teachings of the references themselves, in combination, provide the requisite rationales for combining the teachings. Applicant is also reminded that "[i]t is prima facie

obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). The references themselves are drawn to controlled release compositions comprising interleukins, polymer, BSA and equivalents thereof.

Applicant argues that Lambert does not cure the deficiencies of Huille and/or Singh and that the instant invention does not pertain to the solubility improvement of a drug by way of hydrophobic groups or hydrophobic moieties, but rather where the concentration of the polymer is sufficiently high such that a gelled deposit forms in vitro in an aqueous solution comprising BSA (Remarks,. p. 28). Applicant's argument is noted, but does not render the reference inapplicable, for reasons of record and the reasons set forth above.

Applicant argues that Akiyoshi does describe the spontaneous dissociation of insulin from the polymer when BSA is added, but Applicant argues that this teaches away from the instantly claimed invention (Remarks, p. 28). Applicant's argument is not well taken. The spontaneous dissociation of insulin was at 1.3 mg/ml of BSA at pH 7.4 and 37C (Figure 7). However, Akiyoshi teaches that approximately 15% of insulin remained in complex at a BSA concentration of 50 mg/ml (p. 319). Applicant is also referred to Hora et al., (Biotechnology (NY). 1990 Aug;8(8):755-8, Abstract Only) (cited in response to Applicant's argument). Hora teaches compositions comprising PEG IL-2 using HSA as an excipient which, after an initial burst, releases 2-3% PEG IL-2 per day in a bioactive form continuously over a 20- to 30-day period. The teachings of Akiyoshi, as evidenced by Hora, are commensurate with the instant invention and provide evidence that the serum albumin acts in a matter to provide controlled release of the IL-2 in the composition.

New Claims 41 and 42 are also rejected for the reasons of record and the reasons set forth herein.

Obviousness-Type Double Patenting Rejections

13. Claims 3-7, 9, 10, 12-15, 18-22, 24, and 36-40 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,630,171 (7 October 2003), the Handbook of Chemistry and Physics (Viscosities of Liquids, Section 6, pages 175-179) and Akiyoshi, et al., (J Controlled Release. 1998;54(313-320), and Singh et al., US Patent 5,102,872 (7 April 1992) (previously cited of record), for the reasons of record and the reason set forth herein. Applicant incorporates arguments from the rejection under 35 USC 103(a). Applicant's arguments have been considered, but they are not persuasive for the reasons set forth of record and above. The rejection is maintained.

14. Claims 3-7, 9, 10, 12-15, 17, and 21-26 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3-7, 9-15, and 21-26 of copending Application No. 10/580023, for the reasons of record and the reasons set forth herein.

Applicant argues that the '023 application has the same priority date as the instant application and cannot be used as prior art against the instant application (Remarks, p. 29). Applicant's argument has been fully considered, but it is not persuasive. Applicant appears to misunderstand the requirements of a double patenting rejection. Whether the copending applications have the same benefit/priority date is not germane to a double patenting rejection, as it would be to a rejection under 35 USC 102(e), for example. Applicant is referred to MPEP 804. The rejection is maintained.

15. Claims 3-7, 9, 10, 12-15, 17, 21, 22, and 24-26 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3-7, 9-15, and 21-26 of copending Application No. 10/580037, for the reasons of record and the reasons set forth herein.

Applicant argues that the '037 application has the same priority date as the instant application and cannot be used as prior art against the instant application (Remarks, p. 29). Applicant's argument has been fully considered, but it is not persuasive. Applicant appears to misunderstand the requirements of a double patenting rejection. Whether the copending applications have the same benefit/priority date is not germane to a double patenting rejection, as it would be to a rejection under 35 USC 102(e), for example. Applicant is referred to MPEP 804. The rejection is maintained.

New Objections/Rejections

Claim Objections

16. Claims 3-7, 9, 10, 12-15, 17-26, and 35-42 are objected to because of the following informalities: The claims recite numerous acronyms, including "GH" or "HG." The commonly understood meaning of this acronym is "growth hormone." However, in some embodiments, Applicant appears to use this acronym to mean hydrophobic group. This confusion is exacerbated by the fact that new claim 42 specifically recites the genus of growth hormones. Additionally, Applicant uses the acronym "AP" to represent "active principle" and "PO" to represent "polymers" in the claims. The uses of these shorthand acronyms are unnecessary and confusing. Applicant is required to use the full word or phrase for each instance of acronyms used in the claims to avoid confusion. Additionally, any parenthetical used in the claims should be deleted and the full terminology used. Appropriate correction is required.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Cherie M. Woodward/
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